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10/712,202

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

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3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,202	Applicant(s) HUEBNER ET AL.	
	Examiner JERRY CUMBERLEDGE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9, 11-15, 17-26, 28 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9, 11-15, 17-26, 28 and 31-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 17 and page 18 of Appeal Brief (arguments directed to the modification of Lahille with McTighe), filed 12/04/2008, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Asnis et al. (US Pat. 5,217,462).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5, 6, 9, 11, 13-15, 2-26, 28, 31, 33, 34-38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Asnis et al. (US Pat. 5,217,462).

Asnis et al. disclose a method of compressing a bone, comprising: selecting a bone screw including a shank (Fig. 3) including a thread (Fig. 3, ref. 26) disposed externally for threaded engagement with bone (Fig. 11), the shank defining a long axis (Fig. 11) and a direction of advancement into bone (Fig. 11), and a head (Fig. 3) connected to the shank and defining a plurality of shoulders (Fig. 3, e.g. near ref. 52, near end of ref. 48) disposed at spaced positions generally along the head (Fig. 3), each shoulder facing generally toward the direction of advancement (Fig. 3)(Fig. 11)

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and extending partially or completely around the head (Fig. 3) to define a respective plane disposed orthogonally to the long axis (Fig. 3); and installing the bone screw as a unit in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank (Fig. 11-13). The step of selecting a bone screw includes a step of selecting a bone screw in which the shank has a proximal portion (Fig. 3, portion towards ref. 56) adjacent the head and a distal portion (Fig. 3, portion near ref. 26) spaced from the head, and wherein the thread is restricted to the distal portion (Fig. 3, ref. 26). The step of selecting a bone screw includes a step of selecting a bone screw in which the shoulders are formed by a plurality of ridges (Fig. 3), a plurality of grooves, or both. The step of selecting a bone screw includes a step of selecting a bone screw in which one or more of the plurality of shoulders extend in a closed loop corresponding to a circle (Fig. 3, e.g. near ref. 52, near end of ref. 48). The step of selecting a bone screw includes a step of selecting a bone screw in which the plurality of shoulders have a corresponding plurality of diameters, and wherein the diameters decrease successively toward the shank (Fig. 3). The step of selecting a bone screw includes a step of selecting a bone screw in which the head is shaped generally as a frustum of a cone (Fig. 3, e.g. it tapers). The step of selecting a bone screw includes a step of selecting a bone screw in which the head includes a plurality of steps defined by stepwise decreases in the diameter of the head (Fig. 3), and wherein the plurality of shoulders are included in the plurality of steps (Fig. 3). The step of selecting a bone screw includes a step of selecting a bone screw with a bore that has a widened region (Fig. 3, near ref. 56) configured to receive a tool that

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engages the head. The step of selecting a bone screw includes a step of selecting a bone screw in which the head is rotatably and/or slidably connected to the shank (Fig. 3).

Asnis et al. disclose a method of compressing a bone, comprising: selecting a bone screw including a shank (Fig. 3) including a proximal region (Fig. 3, near ref. 25), a distal region (Fig. 3, near ref. 26), and a thread (Fig. 3, ref. 26) disposed externally for threaded engagement with bone and restricted to the distal region (Fig. 3), and a head (Fig. 3, near ref. 56) connected to the shank (Fig. 3) and spaced from the thread by the proximal region (Fig. 3), the head defining a plurality of spaced shoulders disposed generally along the head (Fig. 3, e.g. near ref. 52, near end of ref. 48), each shoulder extending in a respective plane to describe at least an arc of a circle (Fig. 3); and installing the bone screw as a unit in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank (Fig. 3)(Figs. 11-13). The step of selecting a bone screw includes a step of selecting a bone screw in which the shoulders describe complete circles (Fig. 3). The step of selecting a bone screw includes a step of selecting a bone screw in which the head includes a plurality of steps defined by stepwise decreases in the diameter of the head, and wherein the plurality of shoulders are included in the plurality of steps (Fig. 3). The step of selecting a bone screw includes a step of selecting a bone screw in which the shank defines a long axis (Fig. 3), wherein the head has a maximum diameter (Fig. 3), wherein the head has an axial length that is measured parallel to the long axis (Fig. 3), wherein the head has an aspect ratio defined by the axial length of

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the head relative to the maximum diameter of the head, and wherein the aspect ratio is at least 1:1 (Fig. 3).

Asnis et al. disclose a method of compressing a bone with a bone screw, comprising: forming a hole in the bone (Fig. 10); selecting a bone screw (Fig. 3) having a shank (Fig. 3) and a head (Fig. 3) connected to the shank, the head defining a plurality of shoulders (Fig. 3, e.g. near ref. 52, near end of ref. 48) disposed at spaced positions generally along the head (Fig. 3), each shoulder facing generally toward the direction of advancement (Fig. 11) and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis (Fig. 3); and advancing first the shank and then the head of the bone screw into the hole via threaded engagement of the shank with the bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank (Fig. 3). The step of forming a hole includes a step of forming a bore and a counterbore (Fig. 10), and wherein the step of advancing disposes the head and the shank at least substantially in the counterbore and the bore, respectively (Fig. 10)(Fig. 11). The portion of the bone near the head and the portion of the bone near the shank are separated by a fracture in the bone (Fig. 10). The step of selecting a bone screw includes a step of selecting a bone screw in which one or more of the shoulders slope radially outward (Fig. 3, near ref. 52), generally toward the direction of advancement into bone (Fig. 3)(Fig. 11).

Asnis et al. disclose a method of compressing a bone, comprising: selecting a bone screw (Fig. 3) including a shank (Fig. 3) including a thread (Fig. 3, ref. 26)

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disposed externally for threaded engagement with bone (Fig. 11), the shank defining a long axis (Fig. 3) and a direction of advancement into bone (Fig. 3), and a head connected to the shank (Fig. 3) and including a plurality of spaced shoulders of different diameter (Fig. 3, e.g. near ref. 52, near end of ref. 48), each shoulder facing generally toward the direction of advancement (Fig. 3) and extending partially or completely around the long axis (Fig. 3) in a respective path defining a plane (Fig. 3); and installing the bone screw as a unit in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders and is urged toward a portion of the bone near the shank (Fig. 11). The step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder follows a respective path defining a plane oriented orthogonally to the long axis (Fig. 3). The step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder follows a respective path corresponding to at least an arc of a circle (Fig. 3). The step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder extends completely around the long axis in a closed loop (Fig. 3). The step of selecting a bone screw includes a step of selecting a bone screw in which the head includes at least one generally cylindrical segment disposed at least partially between a pair of the shoulders (Fig. 1, near ref. 50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Asnis et al. (US Pat. 5,217,462).

Asnis et al. disclose the claimed invention except for the step of selecting a bone screw includes a step of selecting a bone screw in which the head and the shank are both part of the same monolithic structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the head and shank of Asnis et al. as part of the same monolithic structure, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Claims 7, 8 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asnis et al. (US Pat. 5,217,462) in view of Danieleto et al. (US Pat. 4,312,336).

Asnis et al. disclose the claimed invention except for the step of selecting a bone screw includes a step of selecting a bone screw that is self-tapping. The step of selecting a bone screw includes a step of selecting a bone screw in which the shank includes a tip region configured to cut a hole in the bone as the bone screw is advanced into the bone. The step of forming a hole is performed by the step of advancing.

Danieletto et al. disclose a method of fixing screws to a bone that comprises using self-tapping screws in order to prevent slacking of the device and prevent micro-fractures from forming in the bone (column 2, lines 8-13).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the screw of Asnis et al. as being self-tapping as taught by Danieletto et al. in order to prevent slacking of the device and prevent micro-fractures from forming in the bone (column 2, lines 8-13).

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asnis et al. (US Pat. 5,217,462) in view of Griggs (US Pat. 4,530,355).

Asnis et al. disclose the claimed invention except for the step of selecting a bone screw includes a step of selecting a bone screw in which the shank and the head define opposing ends of the bone screw and further define an axial bore extending between the opposing ends.

Griggs discloses a method of using a compression device (abstract) that comprises selecting a screw that includes an axial bore extending between the two ends (Fig. 1)(column 4, lines 42-49) in order to insert the screw over a guide wire to aid in directing the insertion screw (column 4, lines 42-49).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Asnis et al. with an axial bore extending between the opposing ends in order to insert the screw over a guide wire to aid in directing the insertion screw (column 4, lines 42-49).

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Asnis et al. (US Pat. 5,217,462) in view of Lahille et al. (US Pat. 5,743,912).

Asnis et al. disclose the claimed invention except for the step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder slopes radially outward generally toward the direction of advancement into bone.

Lahille et al. discloses shoulders which slope radially outward (Fig. 5, ref. 14). This prevents the device from recoiling back out of the hole in which it is placed (column 5, lines 32-35).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the shoulders of Asnis et al. with the radial outward slope as taught by Lahille et al., in order to prevent the device of Lombardo from recoiling back out of the hole in which it is placed (column 5, lines 32-35).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733